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to: Secretary-General of the Council of the European Union

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Subject: COMMISSION REGULATION (EU) No .../.. of **XXX** amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, amisulbrom, cyazofamid, diflufenican, dimoxystrobin, methoxyfenozide and nicotine in or on certain products (Text with EEA relevance)

Delegations will find attached Commission document D021273/02.

Encl.: D021273/02



EUROPEAN COMMISSION

Brussels, **XXX**
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[...](2012) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, amisulbrom, cyazofamid, diflufenican, dimoxystrobin, methoxyfenozide and nicotine in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, amisulbrom, cyazofamid, diflufenican, dimoxystrobin, methoxyfenozide and nicotine in or on certain products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC¹, and in particular Article 14(1)(a) thereof,

Whereas:

- (1) For acibenzolar-S-methyl, cyazofamid and methoxyfenozide maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For amisulbrom, diflufenican, dimoxystrobin and nicotine, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acibenzolar-S-methyl on lettuce and other salad plants including *Brassicaceae* an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.
- (3) As regards amisulbrom, such an application was made for tomatoes, aubergines and lettuce. As regards cyazofamid, such an application was made for horseradish. As regards diflufenican, such an application was made for olives for oil production. As regards dimoxystrobin, such an application was made for rye, mustard seed and sunflower seed. As regards methoxyfenozide such an application was made for leafy vegetables and fresh herbs (except scarole, vine leaves, water cress and witloof).
- (4) In accordance with Article 8 of Regulation (EC) No 396/2005 these applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

¹ OJ L 70, 16.3.2005, p. 1.

- (5) As regards nicotine in wild mushrooms, temporary MRLs were set with a condition to review those MRLs based on the evaluation of new data and information, including any scientific evidence on the natural occurrence or formation of nicotine in wild fungi. The Commission received new data and information from European food business operators, which confirm the presence of nicotine in wild mushrooms at levels compatible with the current MRLs. However, scientific evidence is still not available to demonstrate that nicotine occurs naturally in wild mushrooms and to elucidate its mechanism of formation. Therefore, the management decision taken at the Standing Committee of the Food Chain and Animal Health (SCoCAH) on 11 May 2009 regarding the levels set in wild mushrooms for two years is still valid although, it is appropriate to extend the validity of these MRLs for another two years, pending the availability of such information.
- (6) The European Food Safety Authority, hereinafter "the Authority", assessed the applications and the evaluation reports, examining in particular the risks to the consumer and where relevant to animals and gave reasoned opinions on the proposed MRLs². It forwarded these opinions to the Commission and the Member States and made them available to the public.
- (7) As regards all other applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to these substances via consumption of all food products that may contain these substances, nor the short term exposure due to extreme consumption of the relevant crops and products showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.
- (8) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

² EFSA scientific reports available online: <http://www.efsa.europa.eu>.
European Food Safety Authority; Reasoned opinion on the modification of the existing MRL for acibenzolar-S-methyl in lettuce and other salad plants including Brassicaceae. EFSA Journal 2012; 10(3):2632.
European Food Safety Authority; Reasoned opinion on the setting of new MRLs for amisulbrom in tomatoes, aubergines and lettuce. EFSA Journal 2012;10(4):2686. [29 pp.] doi:10.2903/j.efsa.2012.2686.
European Food Safety Authority; Reasoned Opinion Reasoned opinion on the modification of the existing MRL for cyazofamid in horseradish. EFSA Journal 2012;10(3):2647. [22 pp.] doi:10.2903/j.efsa.2012.2647.
European Food Safety Authority; Reasoned opinion on the modification of the existing MRLs for diflufenican in olives for oil production. EFSA Journal 2012;10(3):2649. [23 pp.] doi:10.2903/j.efsa.2012.2649.
European Food Safety Authority; Reasoned opinion on the modification of the existing MRLs for dimoxystrobin in rye, sunflower seed and mustard seed. EFSA Journal 2012;10(3):2648. [28 pp.] doi:10.2903/j.efsa.2012.2648.
European Food Safety Authority; Reasoned opinion on the modification of the existing MRLs for methoxyfenozide in various leafy vegetables. EFSA Journal 2012;10(4):2667. [30 pp.] doi:10.2903/j.efsa.2012.2667.

Article 1

Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

ANNEX

Annexes II and III to Regulation (EC) No 396/2005 are amended as follows:

- (1) In Annex II, the columns for acibenzolar-S-methyl, cyazofamid and methoxyfenozide are replaced by the following:

[For Official Journal: insert table Annex II existing].

- (2) Annex III is amended as follows:

- (a) Part A is amended as follows:

- (i) the columns for amisulbrom, diflufenican, dimoxystrobin and nicotine are replaced by the following:

[For Official Journal: insert table Annex IIIA existing];

- (b) In Part B, the columns for acibenzolar-S-methyl, cyazofamid and methoxyfenozide are replaced by the following:

[For Official Journal: insert table Annex IIIB existing].